said upper resilient inner sole portion being composed of a plurality of resilient sections, said sections being removably secured on their lower surfaces to said underlying flexible sheet and said sections together forming a substantially smooth surface for engagement by the foot, said sections being individually removable to provide localized pressure relief to selected areas of the foot; and

wherein said resilient sections each comprise at least three layers of progressively different softness and resiliency, with the softest and most resilient layer being closest to the foot;

whereby a relief zone corresponding to an afflicted zone of a foot is provided when one or more of said sections is removed.

REMARKS

Attached to the present amendment are several Declarations, one signed by an officer of Royce Medical Company, the assignee of the present invention, two others signed by Tracy Grim, the lead inventor, and another signed by the undersigned attorney Alan C. Rose.

Now, turning to the rejection, it is respectfully suggested that the Final Rejection was premature in view of the citation of a new reference. In this regard, although there were some minor changes to the claims, the issues were well established by the original claim set, and in view of the citation of and reliance on a new reference, a final rejection should not have been made.

Now, turning to the rejection, it is noted that the enclosed Declarations are believed to overcome the previous objections to the prior submitted declarations.

In addition, the lengthy Declaration of Tracy Grim is particularly to be noted, and will be considered in detail hereinbelow.

Concerning the rejection of claim 37, this claim has been amended to include the antecedent basis for the language under consideration as suggested by the Examiner.

Concerning claim 35, in the Office Action it is stated that "there does not appear to be any structure disclosed which would be described in such a manner". In this regard attention is directed to the left hand portion of Fig. 2 wherein the shoe construction has a "heel portion that

extends only partially up the heel of the user". For the convenience of the Examiner, that Figure of the drawing is included in the body of this amendment.

Concerning claim 38, the language under consideration is "a material which resists compression set". The objection to this language is not understood. Thus, you can bend a soft piece of wire such as solder, and it will remain bent; but if you compress a spring, it will resist the compression set and spring back to its original shape. Similarly as mentioned in col. 2, lines 37 to 40, materials are known which conform to the shape of the anatomy and which keep this configuration. In the present case, there is no such permanent deformation, but the material "resists a compression set". It is therefore respectfully requested that this rejection be withdrawn.

Now, turning to paragraph 7 of the rejection, it is based on a combination of patents identified as Kellerman (5,154,682), Andrews (4,793,078) and Moranaga (4,633,598).

With regard to this rejection, I have spent considerable time with the people from Royce Medical, reviewing the prior art references and the advantages of the invention; and the Declaration of Tracy Grim along with its attachments, were the result of such review. The sections of the Grim Declaration starting with paragraph 6, dealing with the Andrews –078 patent are particularly pertinent and will be repeated here:

> "6. The –078 patent clearly has limitations in that the pressure relief is only allowed in specific areas, and will only accommodate specific sized ulcers. Should an ulcer lie on the edge, or outside of these specific zones, then the pad will become useless from pressure relief function. It is noted that the –078 patent states that "the number, shape and position of the depressions 18 and 18a may be chosen as best suited to the needs of most users", and "Portions may be cut from this insert 19b or it may be cut into pieces to suite the users' requirements". This –078 device obviously was a step in the right direction, but it clearly does not have the advantages of a full grid or array or removable elements. Our present invention with the full grid means that the product can be used to accommodate ulcers anyplace on the foot. Further, at a later date, when a new ulcer or ulcers appear at a different location, the same footgear may be used merely by reinserting the previously removed elements and removing new

elements in the grid at a different location. With the specifically located recesses of the –078 patent, this flexibility and versatility is not present.

7. Considering the Andrews –078 patent from a somewhat different perspective, it involves an insole II and recesses or depressions 18 in fixed locations, which may be filled with inserts 19. Our construction, on the other hand involves an array of resilient elements underlying the entire sole area of the foot. In actual practice, consider how the Andrews –078 device would be marketed. Presumably the manufacturer would make insoles with fixed location recesses as shown in the –078 patent drawings. The doctor treating a patient would remove inserts matching the ulcers on a patients foot. But what happens when the ulcer is not in the exact location of the depressions of the Andrews –078 structure? The doctor would possibly send back to the manufacturer and ask for a new special insole, or the doctor might try to cut the insole in a makeshift way to create a new recess. And similarly, what happens when the ulcer increases in size or decreases in size? Again the Andrews –078 structure with its fixed location depressions or recesses cannot handle the problem. However, our structure readily accommodates both of these problems by having the full array of removable and reinsertable resilient elements. Ulcers anyplace on the foot may be accommodated. If the ulcer increases or decreases in size additional elements may be added or removed. If the ulcer is under the instep or in any location whatsoever, our orthopaedic device can accommodate the situation without the need to go back to the manufacturer for a new device. This structure with these enumerated advantages is not shown or suggested by the Andrews –078 patent.

8. The –682 patent has many limitations regarding its function for the treatment of plantar ulcerations. The primary limitation is that there is no way to completely relieve the pressure under the ulcer site, and this is a requirement for healing these conditions. While the '682 patent can provide pressure "reduction", the continuous layer next to the skin will always provide some pressure and tension on the skin of the foot. This constant pressure and tension can lead to the deformation of fragile skin and closing of the super-thin capillaries located in the skin and fat tissue in the wound area, thereby reducing or eliminating

capillary refill and venous return, both of which are critical to the regeneration and replacement of damaged and necrotic tissue.

9. The reason we shift around at night is due in fact to an autonomic reaction designed to prevent this very issue from occurring to even healthy tissue while we sleep. Our nervous system tells us to shift in our sleep, allowing capillary refill in the skin areas that were bearing weight. If we did not move, then we would get pressure sores in those areas. The people that this –682 product is designed to treat already have systemic problems that limit blood flow to their feet (diabetes, vascular problems, etc.) so a product that would in anyway hinder that flow would be detrimental to the situation. In addition, the feet are the farthest areas on the human body from the heart, making venus return from the feet taxing even in a healthy person, requiring a strong blood pressure to ensure good function, That is why in traditional treatment modalities, complete weight/tension removal has provided the best results, even to the extreme of putting the patient in bed or a wheelchair to eliminate the pressure. (See the attached studies and information for further description of the pressures associated with the foot, ailments, and treatment methods).

10. Another shortcoming of the –682 patent is the low coefficient of friction next to the foot. This would enable the foot to slip and slide within the footgear, causing unnecessary pressure in the toe, sidewalls and heel during the gait cycle, possibly causing new pressure sores or blisters in those areas.

11. The mobility of the removable sections under the smooth top surface is yet another limitation that makes the –682 device unsultable for the treatment of plantar ulcers. These sections cannot move independently under the skin as they are all attached to the surface that is in contact with the skin. Our product which has sections connected on the shoe side of the insole, allows for some independent movement of these sections next to the skin, thereby accommodating the hills and valleys of the traumatized or diseased foot to a much higher extent.

12. In progressive stages of the vascular compromised patient, the bones of the foot actually begin to collapse in the areas of highest stress (i.e., arches fall, metatarsal heads collapse, etc.) until the profile of the normal smooth bottomed foot becomes synonymous to stair steps and even the bottom of ice cream cones! Because a continuous film, as described in the –682 patent, would

certainly have varying degrees of tension depending on how many steps are involved, the design will certainly create peak pressures and tension surrounding and supporting the deepest areas of bony infringement. In our invention, the surface is cut into multiple independent small supportive pillars. These pillars can support the bony prominences of the deformed foot with small independent movements that are not restricted by the tensions of a continuous film, no matter how stretchable or flexible that film is. The micro-motion allowed by these independent pillars reduces both peak pressures and shear forces, both of which are very important in the treatment of the involved "craterous" profile of many patient's feet in the advanced stages of disease.

13. The shape and size of the sections in our product allow for more precise removal of pressure for smaller ulcers, as compared to the larger sections shown and described in the –682 patent.

14. The attached written materials presented as Exhibits A-D bring out the serious nature of diabetic ulcers on the feet, and the fact that improperly treated ulcers often lead to amputation. Where such drastic results may result from improper treatment, a fully appropriate treatment with full relief in the ulcerated area is essential. In Exhbit B attached hereto, a medical study funded by Royce Medical, the assignee of this application, the product of the present invention is compared with the best known available alternative arrangements. As indicated in the graphs and test results, the product of the present invention is superior to the other principal methods or devices, except for casts, which obviously have other problems including access to inspect the foot, for example. It is further noted that the device of the –078 patent lacks the flexibility and versatility, as well as capability for re-use for ulcers in different locations, provided by our invention. In addition, the –682 with its direct contact with the foot clearly has serious shortcomings as discussed above."

In summary, therefore, the attached Declaration of Tracy Grim clearly brings out the unobviousness and the superiority of the Royce invention under consideration. It has enjoyed significant commercial success and approbation in the medical community. Both of these factors

are significant and supplement the cogent reasons for patentability brought out in the Declaration.

The newly cited patent to Moronaga has also been reviewed but it does not have the important features of an array of removable resilient elements immediately adjacent the feet.

In closing, it is noted that this patent application is important to the assignee, and we would greatly appreciate a telephone call from the Examiner following receipt of this response, indicating the Examiner's position, so that a course of action may be considered within one month following the due date. Particularly in view of the questionable early final rejection, the courtesy of a prompt telephone call will be appreciated. The telephone number is set forth below. Thank you.

Respectfully submitted,

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Enclosed:

Declarations
1) Tracy Grim (2)
2) Kent Webster
3) Alan C. Rose
4) Fig. 2 of U.S. Pat. No. 5,763,834

ADDENDUM PAGE

37. A pad for footgear with pressure relief areas for the foot, said pad having a sole area extending for substantially the entire area underlying the foot of a user, comprising:

an underlying flexible sheet and an upper resilient inner sole member extending over and being removably secured to said underlying flexible sheet, said upper resilient inner sole member having a substantially uniform thickness and extending substantially over the entire sole area;

said upper resilient inner sole portion being composed of a plurality of resilient sections, said sections being removably secured on their lower surfaces to said underlying flexible sheet and said sections together forming a substantially smooth surface for engagement by the foot, said sections being individually removable to provide localized pressure relief to selected areas of the foot; and

wherein said resilient sections each comprise at least three layers of progressively different softness and resiliency, with the softest and most resilient layer being closest to the foot;

whereby a relief zone corresponding to an afflicted zone of a foot is provided when one or more of said sections is removed.